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DAVID W. HIGHET, VP AND CHIEF IP COUNSEL
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

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| EXAMINER |
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TOMASZEWSKI, MICHAEL

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3626

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|-------------------------------|-----------------------------|--|
| Office Action Summary | Application No. 09/881,041 | Applicant(s) VONK ET AL. | |
| | Examiner Mike Tomaszewski | Art Unit 3626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Notice To Applicant

1. This communication is in response to the amendment filed on 10/24/06. Claims 21-25 have been added. Claims 1-25 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne et al. (5,867,821; hereinafter Ballantyne), in view of Joao (6,283,761; hereinafter Joao), and in view of Summerell et al. (5,937,387; hereinafter Summerell).

- (A) As per currently amended Claim 1, Ballantyne discloses a system for monitoring health-related conditions of patients, comprising:

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- (1) a plurality of remote monitoring stations, each being adapted to receive patient health-related data pertaining to a respective patient (Ballantyne: col. 2, lines 25-26; col. 8, lines 1-2; col. 9, lines 1-15; Fig. 1-3); and
- (2) a computer network comprising a database containing accumulated health-related data pertaining to health-related conditions and treatment, and at least one data access device adapted to provide a health care provider access to said computer network and said database, said computer network being adapted to receive said patient health-related data from said remote monitoring stations, to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and to revise said accumulated health-related data based on said patient health-related data (Ballantyne: abstract; col. 1, line 65-col. 2, line 63; col. 15, lines 56-65; Fig. 1-12 B).

Ballantyne, however, fails to *expressly* disclose a system for monitoring health-related conditions of patients, comprising:

- (3) said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of

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questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools; and

- (4) said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information relating to the selected treatment program needs to be conveyed to the patient.

Nevertheless, these features are old and well known in the art, as evidenced by Joao and Summerell. In particular, Joao and Summerell disclose a system for monitoring health-related conditions of patients, comprising:

- (3) said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30); and

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- (4) said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information relating to the selected treatment program needs to be conveyed to the patient (Joao: abstract; col. 4, line 26-col. 5, line 54; col. Col. 41, line 56-col. 43, line 29; Fig. 1-15B).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne and Summerell with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

(B) As per previously presented claim 2, Ballantyne discloses a system as claimed in claim 1, wherein:

- (1) each of said remote monitoring stations comprises at least one measuring device, adapted to measure a physiological condition of said respective patient, and to provide data representative of said physiological condition

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for inclusion among said patient health-related data (Ballantyne: col. 11, lines 18-27).

Ballantyne, however, fails to *expressly* disclose a system as claimed in claim 1, wherein:

- (2) said electronic assessment tools allow a health care provider to monitor said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle and determine readiness of the patient for self-management under the selected treatment program.

Nevertheless, these features are old and well known in the art, as evidenced by Summerell. In particular, Summerell discloses a system as claimed in claim 1, wherein

- (2) said electronic assessment tools allow a health care provider to monitor said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle and determine readiness of the patient for self-management under the selected treatment program (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30).

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One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

(C) As per original claim 3, Ballantyne discloses a system as claimed in claim 1, wherein:

said remote monitoring stations are adapted to provide said patient health-related data to said computer network over the Internet (Ballantyne: Fig. 1, 5, 7B)

(D) As per previously presented claim 4, Ballantyne fails to *expressly* disclose a system as claimed in claim 1, wherein:

- (1) said electronic assessment tools are quality of life assessment tools (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30) (Examiner has noted insofar as claim 4 recites "selected from the group consisting of Standard Form-36 (SF-36), Duke Activity Index, guidelines of the Diabetes Quality Improvement Project (DQIP), tools for specific disease state monitoring, depression scales, nutrition assessment tools, quality of life assessment tools," quality of life assessment tools is recited.).

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Nevertheless, these features are old and well known in the art, as evidenced by Summerell. In particular, Summerell discloses a system as claimed in claim 1, wherein:

- (1) said electronic assessment tools are quality of life assessment tools
(Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

- (E) As per original claim 5, Ballantyne discloses a system as claimed in claim 1, wherein:

said computer network is adapted to generate reports, each including health-related information pertaining to a respective said patient (Ballantyne: col. 15, lines 22-67; col. 16, lines 1-13).

- (F) As per original claim 6, Ballantyne fails to *expressly* disclose a system as claimed in claim 1, wherein:

said computer network is adapted to provide said accumulated health-related data stored in said database to organizations financing at least a portion of said treatment programs, and is adapted to receive financial data pertaining to said

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treatment programs from said organizations and to store said financial data in said database. Nevertheless, these features are old and well known in the art, as evidenced by Joao.

In particular, Joao discloses a system as claimed in claim 1, wherein:

said computer network is adapted to provide said accumulated health-related data stored in said database to organizations financing at least a portion of said treatment programs, and is adapted to receive financial data pertaining to said treatment programs from said organizations and to store said financial data in said database (Joao: col. 4, lines 31-47; col. 37, lines 35-47; Fig. 1).

One having ordinary skill would have found it obvious at the time of the invention to include the aforementioned features of Joao within the Ballantyne system with the motivation of facilitating the creation, management, quality, efficiency and effectiveness of healthcare services (Joao: col. 2, lines 38-54).

(G) As per original claim 7, Ballantyne discloses a system as claimed in claim 1, wherein:

each said remote monitoring station receives from its respective said patient said health related data including data pertaining to the cardiovascular system of said patient (Ballantyne: col. 11, lines 18-27).

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4. Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne, in view of Joao, and in view of Seare et al. (5,557,514; hereinafter Seare).

(A) As per previously presented claim 8, Ballantyne fails to *expressly* disclose a method for monitoring health-related conditions of patients, comprising:

- (1) generating from said accumulated health-related data clinical data comprising outcomes of said treatment programs;
- (2) receiving economic data relating to protocols used in said treatment programs;
- (3) aggregating said patient health-related data, said clinical data and said economic data with information comprising population outcomes and generic standards of care; and
- (4) determining from said aggregated data recommendations for improving the treatment programs.

Nevertheless, these features are old and well known in the art, as evidenced by Joao and Seare. In particular, Joao and Seare disclose a method for monitoring health-related conditions of patients, comprising:

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- (1) generating from said accumulated health-related data clinical data comprising outcomes of said treatment programs (Joao: abstract; col. 4, line 26-col. 5, line 54; Fig. 1-15B);
- (2) receiving economic data relating to protocols used in said treatment programs (Seare: abstract; Fig. 1-15);
- (3) aggregating said patient health-related data, said clinical data and said economic data with information comprising population outcomes and generic standards of care (Seare: abstract; Fig. 1-15); and
- (4) determining from said aggregated data recommendations for improving the treatment programs (Seare: abstract; Fig. 1-15).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne and Seare with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Seare with the combined teachings of Ballantyne and Joao with the motivation of assessing treatment programs (Seare: abstract).

The remainder of claim 8 substantially repeats the same limitations as those in claim 1 and therefore, the remainder of claim 8 is rejected for the same reasons given for claim 1 and incorporated herein.

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(B) Claims 9-14 substantially repeat the same limitations as claims 2-7 and therefore, are rejected for the same reasons given for claims 2-7 and incorporated herein.

5. Claim 15-21 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne, Joao, Russek (5,319,355; hereinafter Russek), and in view of Soll et al. (US 2003/0055679).

(A) As per amended currently amended claim 15, Ballantyne discloses a method for managing health-related conditions of patients, comprising:

- (1) collecting said healthcare data by using each said healthcare manager to collect respective health-related data for each respective patient in their said group of patients (Ballantyne: col. 2, lines 33-35; Fig. 11A-11D);
- (2) controlling a computer network to receive said health-related data from each of said healthcare managers, and to store said health-related data pertaining to each said patient in a database, said database further including accumulated data pertaining to health-related conditions and treatments (Ballantyne: col. 12, lines 36-67 and col. 13, lines 1-18; Fig. 11A-11D); and

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- (3) updating said accumulated data in said database based on said health-related data provided by said healthcare managers (Ballantyne: col. 12, lines 33-35).

Ballantyne, however, fails to *expressly* disclose a method for managing health-related conditions of patients, comprising:

- (4) assigning healthcare managers to said patients, such that each said healthcare manager is assigned to a respective group of said patients;
- (5) coordinating each said healthcare manager with at least one member of a primary care team to establish a treatment plan for each respective patient in their said group of patients based on said health-related data pertaining to that respective patient and said accumulated data;
- (6) determining whether each respective patient is suitable for participation in a treatment program;
- (7) wherein the determining step comprises the steps of:
 - (a) obtaining agreement from a respective patient to participate in a treatment program; and
 - (b) receiving approval from a payer who will pay for the treatment program;
- (8) wherein the controlling step comprises the steps of:

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- (a) receiving health-related data for a respective patient comprising assessment of the patient's medical, psychological and environmental conditions; and
- (b) receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and the assessment, the plan of care being used in the establishment of the treatment program for the patient.

Nevertheless, these features are old and well known in the art, as evidenced by Joao and Soll. In particular, Joao and Soll disclose a method for managing health-related conditions of patients, comprising:

- (4) assigning healthcare managers to said patients, such that each said healthcare manager is assigned to a respective group of said patients (Russek: col. 9, lines 29-32);
- (5) coordinating each said healthcare manager with at least one member of a primary care team to establish a treatment plan for each respective patient in their said group of patients based on said health-related data pertaining to that respective patient and said accumulated data (Joao: col. 4, lines 33-39 and col. 12, lines 22-43);

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- (6) determining whether each respective patient is suitable for participation in a treatment program (Soll: abstract; ¶ [0058]; Fig. 1-27);
- (7) wherein the determining step comprises the steps of:
 - (a) obtaining agreement from a respective patient to participate in a treatment program (Soll: abstract; ¶ [0097]; Fig. 1-27); and
 - (b) receiving approval from a payer who will pay for the treatment program (Joao: abstract; col. 16, lines 38-65; Fig. 1-15B);
- (8) wherein the controlling step comprises the steps of:
 - (a) receiving health-related data for a respective patient comprising assessment of the patient's medical, psychological and environmental conditions (Joao: abstract; col. 12, lines 43-50; col. 16, lines 38-65; Fig. 1-15B);
 - (b) receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and the assessment, the plan of care being used in the establishment of the treatment program for the patient (Soll: abstract; ¶ [0058]; Fig. 1-27).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne, Russek and Soll with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

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One having ordinary skill would have found it obvious at the time of the invention to combine the teachings of Russek with the combined teachings of Ballantyne, Joao, and Soll with the motivation of providing efficient and reliable communications concerning the medical conditions of patients (Russek: col. 3, lines 28-29).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Soll with the combined teachings of Ballantyne, Joao and Russek with the motivation of providing a system and method of healthcare (Soll: ¶ [0014]).

(B) Claims 16-20 substantially repeat the same limitations as those in claims 1-7 and therefore, are rejected for the same reasons given for claims 1-7 and incorporated herein.

(C) As per new claim 21, Ballantyne fails to *expressly* disclose a method as claimed in claim 15, wherein collecting healthcare data comprises said healthcare managers developing a client plan of care (CPOC) and a medical plan of care (MPOC), the CPOC is developed during the interview with the patient, and the MPOC is developed with at least one member of the primary care team.

Nevertheless, these features are old and well known in the art, as evidenced by Joao. In particular, Joao discloses a method as claimed in claim 15, wherein collecting healthcare data comprises said healthcare managers developing a client plan of care (CPOC) and a medical plan of care (MPOC), the CPOC is developed during the

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interview with the patient, and the MPOC is developed with at least one member of the primary care team (Joao: col. 4, lines 40-47).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne, Russek and Soll with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

(D) As per new claim 23, Ballantyne discloses a method of establishing a treatment program for a patient comprising:

- (1) collecting healthcare data by using said healthcare managers to collect respective health-related data for each of their assigned said patients (Ballantyne: col. 2, lines 33-35; Fig. 11A-11D); and
- (2) controlling a computer network to receive said health-related data from each of said healthcare managers, and to store said health-related data pertaining to each of said patients in a database, said database further including accumulated data pertaining to health-related conditions and treatments (Ballantyne: col. 12, lines 36-67 and col. 13, lines 1-18; Fig. 11A-11D);

Ballantyne, however, fails to *expressly* disclose a method of establishing a treatment program for a patient comprising:

- (3) assigning healthcare managers to patients;
- (4) determining whether each of said patients is suitable for participation in a treatment program;
- (5) said healthcare managers developing a respective client plan of care (CPOC) for each of their assigned said patients by interviewing them if they are selected for participation, and developing a medical plan of care (MPOC) comprising a treatment program for each of their assigned said patients in cooperation with a primary care team comprising at least one of primary care physicians, hospitals and specialists;
- (6) coordinating said healthcare managers with at least one member of the primary care team to ensure the treatment programs are followed by respective said patients, tracking any changes to the MPOC and updating members of the primary care team regarding the changes; and
- (7) updating said accumulated data in said database based on said health-related data provided by said healthcare managers, including revisions to the CPOCs and MPOCs for respective said patients.

Nevertheless, these features are old and well known in the art, as evidenced by Joao, Russek, and Soll. In particular, Joao, Russek, and Soll disclose a method of establishing a treatment program for a patient comprising:

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- (3) assigning healthcare managers to patients (Russek: col. 9, lines 29-32);
- (4) determining whether each of said patients is suitable for participation in a treatment program (Soll: abstract; ¶ [0058]; Fig. 1-27);
- (5) said healthcare managers developing a respective client plan of care (CPOC) for each of their assigned said patients by interviewing them if they are selected for participation, and developing a medical plan of care (MPOC) comprising a treatment program for each of their assigned said patients in cooperation with a primary care team comprising at least one of primary care physicians, hospitals and specialists (Joao: col. 4, lines 40-47);
- (6) coordinating said healthcare managers with at least one member of the primary care team to ensure the treatment programs are followed by respective said patients, tracking any changes to the MPOC and updating members of the primary care team regarding the changes (Joao: col. 4, lines 33-39; col. 7, lines 43-48; col. 12, lines 22-43); and
- (7) updating said accumulated data in said database based on said health-related data provided by said healthcare managers, including revisions to the CPOCs and MPOCs for respective said patients (Joao: col. 4, lines 33-39; col. 7, lines 43-48; col. 12, lines 22-43).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne,

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Russek and Soll with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

One having ordinary skill would have found it obvious at the time of the invention to combine the teachings of Russek with the combined teachings of Ballantyne, Joao, and Soll with the motivation of providing efficient and reliable communications concerning the medical conditions of patients (Russek: col. 3, lines 28-29).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Soll with the combined teachings of Ballantyne, Joao and Russek with the motivation of providing a system and method of healthcare (Soll: ¶ [0014]).

(E) As per new claim 24, Ballantyne fails to *expressly* disclose a method as claimed in claim 23 further comprising:

- (1) scheduling conferences between said patients and said members of the primary care team; and
- (2) documenting patient-related communications during the conference and during non-scheduled patient-related communications for storage in said database.

Nevertheless, these features are old and well known in the art, as evidenced by Joao. In particular, Joao discloses a method as claimed in claim 23 further comprising:

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- (1) scheduling conferences between said patients and said members of the primary care team (Joao: col. 4, lines 54-55); and
- (2) documenting patient-related communications during the conference and during non-scheduled patient-related communications for storage in said database (Joao: col. 16, lines 38-65).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne, Russek and Soll with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

(F) As per new claim 25, Ballantyne fails to *expressly* disclose a method as claimed in claim 23 further comprising:

- (1) said healthcare managers following clinical encounter schedules to communicate with their said patients;
- (2) using scripts to communicate with said patients during the clinical encounters; and
- (3) assessing said patients' physical and psychological responses.

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Nevertheless, these features are old and well known, as evidenced by Joao. In particular, Joao discloses a method as claimed in claim 23 further comprising:

- (1) said healthcare managers following clinical encounter schedules to communicate with their said patients (Joao: col. 4, lines 54-55);
- (2) using scripts to communicate with said patients during the clinical encounters (Joao: col. 19, lines 59-64); and
- (3) assessing said patients' physical and psychological responses (Joao: col. 16, lines 38-65; Examiner also notes that Joao incorporates U.S. Pat. No. 5,961,332 by reference that teaches assessing psychological responses as well. See Joao: col. 12, lines 48-50.).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne, Russek and Soll with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne, Joao, Russek, in view of Soll, and in view of Official Notice.

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(A) As per new claim 22, Ballantyne fails to *expressly* disclose a method as claimed in claim 15, wherein the determining comprises excluding a respective patient based on selected criteria comprising the patient is a minor, the patient has not received a selected diagnosis, and the patient cannot communicate effectively, and including a respective patient based on selected criteria comprising having a selected primary diagnosis and being at risk for future hospital admissions.

Nevertheless, Examiner takes Official Notice of the technique of “excluding” patients from treatment programs based on various criteria such as those claimed by Applicant. For example, it is well established that minors are often excluded from certain healthcare treatment plans, such as abortions, cosmetic surgeries, and the like. Similarly, Examiner also takes Official Notice of the technique of “including” a patient based on various criteria such as those claimed by Applicant. For example, physicians routinely subject a patient to a diagnosis and then formulate a treatment plan based on the primary diagnosis of the patient. As such, Examiner respectfully submits that the features of claim 22 are old and notoriously well known. Moreover, Examiner submits that these features were developed and widely used well prior to Applicant’s claimed invention.

Response to Arguments

7. Applicant's arguments filed 10/24/06 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 10/24/06.

(A) On pages 10-12 of the 10/24/06 response, Applicant argues that Summerell teaches away and therefore does not render the claimed invention obvious. Essentially, Applicant argues that Summerell, unlike Applicant's claimed invention, seeks to provide a tool for users to select their own wellness plan without involvement of a health care provider.

In response, Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Examiner relied upon the combined teachings of Ballantyne, Joao, and Soll. For example, Joao teaches "[a]ny patient, user, provider, payer, and/or intermediary, may utilize the present invention [i.e., disease management network] in the same, similar and/or analogous manner." See Joao: col. 4, lines 30-33. In other words, Joao teaches the concept of involving a health care provider in devising a

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wellness plan for patients. Moreover, Examiner respectfully submits that Summerell merely expands upon one embodiment rather than teaching away from Applicant's claimed invention.

Furthermore, Examiner notes that a recitation of the intended use (i.e., involving a health care provider) of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

(B) On pages 12-14 of the 10/24/06 response, Applicant argues that impermissible hindsight reconstruction was used to pick and choose among the cited references' purported disclosures to render claim 1 obvious using Applicant's claimed invention as a guide.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

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(C) On page 14 of the 10/24/06 response, Applicant argues that neither Seare nor Ballantyne disclose a computer network for establishing treatment programs for said patients based on their respective patient health-related data and accumulated health-related data, as recited in claim 8.

In response, Examiner respectfully submits that a broad, yet reasonable, interpretation of Ballantyne and Seare does indeed disclose the aforementioned features. For example, Ballantyne teaches the compilation of patient medical and emergency data (i.e., accumulated health-related data) and the provision of medical treatment (Ballantyne: col. 10, line 8; col. 15, line 39-col. 16, line 14). This data in turn dictates the treatments that will be administered or that may be required (i.e., establishing treatment programs for said patient based on their health-related data). For example, a blood dialysis treatment (i.e., treatment program) will be based upon the blood type of a patient (i.e., patient accumulated health-related data).

Moreover, Examiner respectfully submits that Examiner did not rely solely on the teachings of Seare and Ballantyne, but the combined teachings of Summerell and Joao as well. As such, Joao also teaches a computer network for establishing treatment programs for patients based on their health-related data (Joao: col. 4, lines 40-47).

(D) On page 14 of the 10/24/06 response, Applicant argues that Seare does not disclose or suggest aggregating population outcomes and generic standards of care with other data, as recited in claim 8. Applicant argues further that Joao does not disclose generating clinical data comprising outcomes of treatment programs.

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In response, Examiner respectfully submits that a broad, yet reasonable, interpretation of Seare and Joao does indeed disclose the aforementioned features. For example, Seare teaches analyzing "historical treatment patterns" and "patient outcome" data (i.e., population and generic standards of care data) (Seare: col. 1, lines 20-33). Joao, on the other hand, discloses an exhaustive list of data including, *inter alia*, evaluation of treatments (i.e., outcomes) and treatment standards (i.e., generic standards of care) (Joao: col. 28, lines 41-43; col. 38, lines 55-56). Moreover, Joao teaches the aggregation of such data as well. See Joao: col. 16, line 33-col. 20, line 20).

(E) On page 15 of the 10/24/06 response, Applicant argues that if Seare can provide outcome information from medical provider billing data that may arguably teach clinical data as claimed, then such outcome data cannot be population outcome information as claimed. Applicant argues further that since the outcomes in Fig. 4 of Seare are only available from the new billing data, they are not population outcomes as claimed.

In response, Examiner respectfully submits that the combined teachings of Ballantyne, Joao, Seare, and Soll do indeed teach the aforementioned features. For example, see § 7. (D), *supra*.

(F) On pages 15-16 of the 10/24/06 response, Applicant argues that nothing in Soll discloses or suggests receiving a plan of care as a result of an interview for use in the establishment of a treatment program.

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In response, Examiner respectfully submits that a broad, yet reasonable, interpretation of Soll does indeed disclose the aforementioned features. For example, Soll teaches a medical treatment system that analyzes input from the patient (i.e., an interview) so that health care can be delivered accordingly (i.e., establishment of a treatment program).

(G) Applicant's remaining arguments within the response filed 10/24/06 rely upon or re-hash the issues addressed above and therefore, are moot in view of the responses given in §§ 7. (A) – (F), *supra*, and incorporated herein.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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MT



Robert Morgan
Robert Morgan
Patent Examiner
Artunit 3626